Application No.: 10/646,361 Docket No.: TEVNHC 3.0-587

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of claims:

- (previously presented) A dry powder inhalation composition comprising,
 - (a) medicament particles, and
- (b) a mixture of lactose particles with a VMD of between about 70 and about 120 microns and a diameter of less than 250 microns, wherein up to 96% by weight of the lactose particles are less than 150 microns in diameter and wherein up to 25% by weight of the lactose particles are less than 5 microns in diameter.
- 2. (currently amended) A dry powder inhalation composition according to Claim 1, wherein up to 85% by weight of the lactose particles mixture is are less than about 90 microns in diameter.
- 3. (currently amended) A dry powder inhalation composition according to Claim 1, wherein up to 37% by weight of the lactose particles mixture is are less than about 60 microns in diameter.
- 4. (currently amended) A dry powder inhalation composition according to Claim 1, wherein up to 35% by weight of the lactose particles mixture is are less than 30 microns in diameter.
- 5. (currently amended) A dry powder inhalation composition according to Claim 1, wherein up to 31.5% by weight

of the lactose particles mixture is are less than 15 microns in diameter.

- 6. (currently amended) A dry powder inhalation composition according to Claim 1, wherein up to 30% by weight of the lactose particles mixture is are less than 10 microns in diameter.
- 7. (currently amended) A dry powder inhalation composition according to Claim 1, wherein between 6.5 and 24.5% by weight of the lactose particles mixture is are less than 5 microns in diameter.
- 8. (original) A dry powder inhalation composition according to Claims 1 or 7, comprising up to 10% by weight of medicament particles.
- 9. (previously presented) A dry powder inhalation composition according to Claim 1, wherein the medicament particles are formoterol or a pharmaceutically acceptable derivative thereof.
- 10. (previously presented) A dry powder inhalation composition according to Claim 1, wherein the medicament particles are formoterol fumarate dihydrate.
- 11. (previously presented) A multidose dry powder inhaler comprising a dry powder inhalation composition according to Claim 1.
- 12. (currently amended) A method for the administration of a particulate medicament, comprising inhalation from a MDPI

Application No.: 10/646,361 Docket No.: TEVNHC 3.0-587

<u>multidose dry powder inhaler</u> of a dry powder inhalation composition according to Claim 1.

13. (new) The dry powder inhalation composition of claim
1, wherein said mixture of lactose particles is characterized
by the particle size distribution of the following table

Parameters	Mean	Range
VMD	97 μm	89-110
GSD	4.4	2.2-4.9
< 5 μm	13.1%	8.0%-24.0%
< 10 μm	21.6%	14.2%-28.5%
< 15 μm	24.5%	15.0%-31.0%
< 30 μm	26.5%	16.0%-34.0%
< 60 µm	29.6%	18.9%-36.1%
< 90 μm	44.5%	34.8%-50.8%
< 150 μm	87.7%	83.9%-93.5%
< 174 μm	96.0%	93.8%-98.9%
< 250 μm	100%	100%

- 14. (new) A dry powder inhalation composition comprising,
- (a) medicament particles, and
- (b) a mixture of lactose particles characterized by the particle size distribution of the following table

Size/µm	% Cumulative Undersize	
	Target	Range
< 10	11.0	8-13.5
< 30	17.5	10-25
< 60	31.0	20-42

Application No.: 10/646,361 Docket No.: TEVNHC 3.0-587

< 90	45.0	30-60
< 174	> 90	-
< 250	100	-

- 15. (new) A dry powder inhalation composition comprising,
- (a) medicament particles, and
- (b) a mixture of lactose particles prepared by a method comprising blending a portion of fine lactose particles and a portion of coarse lactose particles, wherein said portion of fine lactose particles has a mean particle diameter of less than 10 microns, and wherein said portion of coarse lactose particles is prepared by a method comprising collecting lactose particles on a mesh with mesh size of 63 microns after passing through a mesh with mesh size of 90 microns.